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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,306	12/12/2003	Stephen L. Crooks	54913US116	1679

32692 7590 04/19/2004

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,306	<b>Applicant(s)</b> CROOKS ET AL.	
	<b>Examiner</b> Evelyn Huang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### **DETAILED ACTION**

1. Claims 15-17 are pending. Claims 1-14 have been canceled according to the preliminary amendment filed on 12-12-2003.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant 'inducing cytokine biosynthesis' embraces abnormal and normal cytokine biosynthesis. The latter would possess no physiopathological effect correlated to a disease or disorder that a patentable utility would be found in the treatment thereof. Furthermore, recitation of the mechanism without the end result as in the instant would have no utility and would be rejected under 101 as follows.

#### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention lacks patentable utility for reasons set forth in paragraph 2 above.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The compound of instant claim 15 is an intermediate compound for making the sulfonamide compound of Example 268. The pharmaceutical composition comprising the intermediate compound of claim 15 and the method of inducing cytokine biosynthesis thereof are not described in the specification. Furthermore, the method of inducing cytokine biosynthesis reaches out to activities/conditions/diseases mediated by cytokine not yet identified.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. \*\*\*.

- a. *Nature of the invention.*

The instant invention is drawn to a sulfonamide substituted imidazoquinoline for inducing cytokine biosynthesis in an animal.

- b. *State of the prior art and the level of the skill in the art.*

According to Stedman's Medical Dictionary, cytokine is a general term for any of numerous hormonelike, low molecular-weight proteins, secreted by various cell types, including interferon, interleukin, lymphokine and chemokines etc. While broad spectrum of activities have been attributed to the cytokines, there is only limited understanding of the mechanisms that lead

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to one activity over another when a specific cytokine is involved in a specific biological reaction (Cohen et al . American Journal of Clinical Pathology 1996, 105(5):589-598, abstract). At the time of the invention, little is known about the true roles played by chemokines in normal and disease physiology (Rollins BJ. Blood, 1997, 90(3): 909-928, page 920, Conclusions).

Synthetic inducers of interferon are known (Fleming, 3692907, column 23, claim 32). Imidazo[4,5-c]quinolin-4-amine derivatives are also known to induce interferon biosynthesis (Gerster, 5266575, columns 9-10, PTO-1449). Certain imidazo[4,5-c] quinoline compounds have been shown to induce TNF and IL-1 production (Testerman, abstract, PTO-1449). However, a compound effective in inducing cytokines of all types has not been described. At the time of the invention, there is only limited understanding of the mechanisms that lead to one activity over another when a specific cytokine is involved in a specific biological reaction.

The level of the skill in the cytokine biosynthesis art is high.

c. *Predictability/unpredictability of the art.*

The high degree of unpredictability is well recognized in the cytokine biosynthesis art. A slight change in the structure of the compound would drastically change its biological activity as evidenced in the different values of structurally similar compounds in the interferon bioassay and the different anti-viral activities by the same compounds in the type II Herpes simplex-infected guinea pigs (Gerster, columns 9-10). Structurally similar imidazo[4,5-c] quinoline compounds have different profiles in the induction of the different cytokines (Testerman, page 367, 368, Table 1 and Table 2). Furthermore, a correlation between the in vitro data and in vivo activity has not been established, as the dose responses for given effects in vitro may not be relevant in vivo (Rollins, page 909, column 2).

d. *Amount of guidance/working examples.*

The preparation of the inventive compound has been described (Example 236). The ability of the example compounds to induce interferon and TNF in human blood cells is shown on pages 126-133 of the specification. No in vivo procedures are described.

e. *Breadth of the claims.*

Applicant's assertion that the inventive compound is an effective inducers of all types of cytokines involving in all the broad spectrum of activities, and reaching out into activities/conditions/diseases not yet identified, does not commensurate with the scope of the

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objective enablement, especially in view of the high degree of unpredictability and the working examples limiting to induction of interferon and TNF (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient guidance and teaching have been provided by the specification (paragraphs c-e above), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compound as claimed without undue experimentation.

***Conclusion***

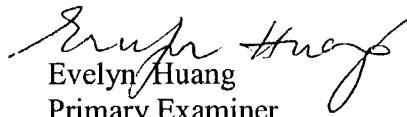
6. Claim 15 is allowed.

Crooks (6541485, PTO-1449) discloses a 1-(2-aminoethyl)- 2-ethoxymethyl-1H-imidazo[4,5-c]quinoline-4-amine intermediate compound (column 51, lines 27-28). The instant, however, has a 1-(2-amino-2-methylpropyl) substituent instead of Crooks's 1-(2-aminoethyl). Motivation to modify Crook's intermediate compound to arrive at the instant is lacking.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625